

**REMARKS**

Applicants respectfully request reconsideration of this application in view of the above Amendment and the following remarks.

Claims 1, 23, and 44 have been amended to provide that the encoded GHRH has a sequence of SEQ ID NO.: 6. Applicants respectfully direct the Examiner's attention to the Office Action mailed on May 9, 2006, Page 6, in which the Examiner indicated that the specification disclosed those 48 encoded GHRH sequences corresponding to SEQ ID NO.: 6 and that the specification showed that Applicants were in possession of those GHRH sequences of SEQ ID NO.: 6. For the purpose of complying with the restriction requirement of January 11, 2006, Applicants have also amended Claims 1, 23, and 44 to provide that the encoded GHRH has a sequence of SEQ ID NO.: 1 in particular.

In response to the Examiner's comments in the Advisory Action dated February 23, 2007, Applicants have omitted the phrase "corresponding to" from the amended claims. Instead, Applicants state that the encoded GHRH has a sequence of SEQ ID NO.:1 or SEQ ID NO.:6. Applicants assert that this claim terminology clearly indicates the metes and bounds of the claim limitations.

Claims 1, 23, and 44 have also been amended to provide that the constant current electrical pulse is maintained under a threshold to allow one to reduce cell heating and create less cell death. Support for this amendment is found in the Specification at Paragraph 156.

Claims 30 and 48 have been amended to correct the spacing in "SEQID." Claims 28, 30, 34, 37, 38, and 40 – 42 have been amended to correct the dependency of these claims, which was mistakenly listed as dependency from Claim 26, rather than independent Claim 23. Finally, Claims 20, 39, and 57 have been cancelled.

Pending in this application are Claims 1-4, 7-9, 11, 15-19, 22, 23, 26-28, 30, 34-38, 40-45, 47, 48, and 52-56.

**I. Claim Objections**

The Examiner has objected to Claims 1, 23, and 44 as being “ungrammatical.” Applicants have amended these claims to delete the terminology the Examiner has objected to.

The Examiner has suggested the removal of the parentheses around “SEQ ID NO.: 1” in Claims 1, 20, 23, 39, 44, and 57. Applicants have amended Claims 1, 23, and 44 in accordance with the Examiner’s suggestions. Claims 20, 39, and 57 have been canceled.

Finally, the Examiner has objected to Claims 30, 48, and 86 and requested the insertion of a space within the term “SEQID.” Applicants have amended Claims 30 and 48 in accordance with the Examiner’s suggestion. Claim 86, being withdrawn, has not been amended.

In view of these amendments, Applicants respectfully request that the Examiner withdraw the claim objections.

**II. 35 U.S.C. §112, First Paragraph, New Matter**

Claims 1-4, 7-9, 11, 15-19, 22, 23, 26-28, 30, 34-38, 40-45, 47, 48, and 52-56 stand rejected under 35 U.S.C. §112, first paragraph, for containing new matter that the Examiner asserts is not described in the specification. The Examiner asserts that the claim limitation “95% identical to (SEQ ID NO.: 1)” is not supported in the specification. Applicants have deleted this claim terminology from independent Claims 1, 23, and 44. In view of this, Applicants respectfully request that the Examiner withdraw these claim rejections.

**III. 35 U.S.C. §112, First Paragraph, Written Description**

Applicants wish to thank the Examiner for indicating in the Advisory Action dated February 23, 2007 that the rejection of Claims 1-4, 7-9, 11, 15-20, 22, 23, 26-28, 30, 34-45, 47, 48, and 52-57 under 35 U.S.C. §112, first paragraph, has been withdrawn.

**IV. 35 U.S.C. §103(a)****A. Schwartz in view of Aihara and Simon**

Claims 1-4, 7-9, 11, 18-19, 22, 23, 26-28, 30, 37-38, 40-45, 47, 48, and 55-56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over International Patent Publication No. WO 2002/061037 to Schwartz et al. (“Schwartz”) in view of the Nature Biotech. Publication by Aihara et al. (“Aihara”) and U.S. Patent No. 6,928,318 to Simon (“Simon”). The Examiner asserts that Schwartz teaches the injection of a nucleic acid represented by SEQ ID NO.: 11 and that Aihara teaches electroporation at the injection site. In the previous response filed by Applicants, Applicants argued that Schwartz in combination with Aihara did not teach the use of a constant current pulse in electroporation. In response to these arguments, the Examiner has cited an additional reference, Simon, which assertedly teaches the use of a constant current pulse in electroporation. Applicants respectfully assert that Simon does not teach the use of a constant current electrical pulse that meets the limitations of the claims as amended.

Claims 1, 23, and 44 have been amended to provide that, in the claimed step of applying a **constant current electrical pulse** to the plurality of electrodes, the constant current pulse is **maintained under a threshold** to allow one to reduce cell heating and create less cell death. Support for this amendment is found in Paragraph 156 of the Specification.

Simon does not teach maintaining a constant current pulse under a threshold to enable the user to reduce cell heating and create less cell death. Simon’s electroporation device records electrical parameters concurrently with biological responses only to correlate them and assess the performance of the system. See Simon, col. 5, l. 59 – col. 6, l. 11. Thus, Simon’s system provides no teaching of maintaining the actual constant current electrical pulse below a threshold. This is significantly different from the claims, which require maintaining the constant current electrical pulse below a threshold to reduce cell heating and create less cell death. Because Simon is only concerned with the correlation of electrical parameters with biological responses and not with the avoidance of cell heating and cell death, Simon’s teachings with regard to electroporation cannot meet the claim limitations. There is nothing in Simon that

would teach or suggest maintaining the constant current electrical pulse below a threshold, which is required by the claims.

For these reasons, Claims 1-4, 7-9, 11, 18-19, 22, 23, 26-28, 30, 37-38, 40-45, 47, 48, and 55-56 are patentable over Schwartz in view of Aihara and Simon.

B. Schwartz in view of Aihara, Simon, and Fewell

Claims 15-17, 34-36, and 52-54 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz in view of Aihara, Simon, and U.S. Patent Publication No. 2003/0109478 to Fewell ("Fewell"). These claims pertain to the use of a transfection-facilitating polypeptide, which the Examiner asserts is taught by Fewell. Applicants respectfully assert that Schwartz, Aihara, Simon, and Fewell in combination do not teach or suggest all of the limitations of the claimed subject matter, as amended.

In particular, the Examiner cites to Simon as assertedly teaching constant current electroporation. However, Claims 1, 23, and 44 have been amended to provide that, in the claimed step of applying a constant current electrical pulse to the plurality of electrodes, the constant current pulse is maintained under a threshold to allow one to reduce cell heating and create less cell death. By contrast, Simon does not teach maintaining a constant current pulse under a threshold to enable the user to reduce cell heating and create less cell death. Simon's electroporation device records electrical parameters concurrently with biological responses only to correlate them and assess the performance of the system. See Simon, col. 5, l. 59 – col. 6, l. 11. Thus, Simon's system provides no teaching of maintaining the actual constant current electrical pulse below a threshold. This is significantly different from the claims, which require maintaining the constant current electrical pulse below a threshold to reduce cell heating and create less cell death. Because Simon is only concerned with the correlation of electrical parameters with biological responses and not with the avoidance of cell heating and cell death, Simon's teachings with regard to electroporation cannot meet the claim limitations. There is nothing in Simon that would teach or suggest maintaining the constant current electrical pulse below a threshold, which is required by the claims.

For these reasons, Claims 15-17, 34-36, and 52-54 are patentable over Schwartz in view of Aihara, Simon, and Fewell.

## **V. Double Patenting**

### **A. U.S. Patent No. 6,423,693, in view of Schwartz and Simon**

Claims 1-4, 7-9, 11, 18-19, 22, 23, 26-28, 30, 37-38, 40-45, 47, 48, and 55-56 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 21-23 of U.S. Patent No. 6,423,693 (“the ‘693 Patent”), in view of Schwartz and Simon. The Examiner asserts that Claims 21-23 of the ‘693 Patent pertain to methods for delivering an expression vector encoding GHRH, that Schwartz teaches SEQ ID NO.: 1 and a synthetic, muscle-specific promoter, and that Simon teaches constant current electroporation. Applicants respectfully disagree and assert that the ‘693 Patent, Schwartz, and Simon in combination do not teach or suggest all of the subject matter of the amended claims.

In particular, the Examiner cites to Simon as assertedly teaching constant current electroporation. However, Claims 1, 23, and 44 have been amended to provide that, in the claimed step of applying a constant current electrical pulse to the plurality of electrodes, the constant current pulse is maintained under a threshold to allow one to reduce cell heating and create less cell death. By contrast, Simon does not teach maintaining a constant current pulse under a threshold to enable the user to reduce cell heating and create less cell death. Simon’s electroporation device records electrical parameters concurrently with biological responses only to correlate them and assess the performance of the system. See Simon, col. 5, l. 59 – col. 6, l. 11. Thus, Simon’s system provides no teaching of maintaining the actual constant current electrical pulse below a threshold. This is significantly different from the claims, which require maintaining the constant current electrical pulse below a threshold to reduce cell heating and create less cell death. Because Simon is only concerned with the correlation of electrical parameters with biological responses and not with the avoidance of cell heating and cell death, Simon’s teachings with regard to electroporation cannot meet the claim limitations. There is nothing in Simon that would teach or suggest maintaining the constant current electrical pulse below a threshold, which is required by the claims.

For these reasons, Claims 1-4, 7-9, 11, 18-19, 22, 23, 26-28, 30, 37-38, 40-45, 47, 48, and 55-56 are patentably distinct from Claims 21-23 of the '693 Patent, in view of Schwartz and Simon.

B. U.S. Patent No. 6,423,693, in view of Schwartz, Simon, and Fewell

Claims 15-17, 34-36, and 52-54 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 21-23 of U.S. Patent No. 6,423,693 ("the '693 Patent"), in view of Schwartz, Simon, and Fewell. The Examiner asserts that Claims 21-23 of the '693 Patent pertain to methods for delivering an expression vector encoding GHRH, that Schwartz teaches SEQ ID NO.: 1 and a synthetic, muscle-specific promoter, that Simon teaches constant current electroporation, and that Fewell teaches a transfection-facilitating polypeptide. Applicants respectfully disagree and assert that the '693 Patent, Schwartz, Simon, and Fewell in combination do not teach or suggest all of the subject matter of the amended claims.

In particular, the Examiner cites to Simon as assertedly teaching constant current electroporation. However, Claims 1, 23, and 44 have been amended to provide that, in the claimed step of applying a constant current electrical pulse to the plurality of electrodes, the constant current pulse is maintained under a threshold to allow one to reduce cell heating and create less cell death. By contrast, Simon does not teach maintaining a constant current pulse under a threshold to enable the user to reduce cell heating and create less cell death. Simon's electroporation device records electrical parameters concurrently with biological responses only to correlate them and assess the performance of the system. See Simon, col. 5, l. 59 – col. 6, l. 11. Thus, Simon's system provides no teaching of maintaining the actual constant current electrical pulse below a threshold. This is significantly different from the claims, which require maintaining the constant current electrical pulse below a threshold to reduce cell heating and create less cell death. Because Simon is only concerned with the correlation of electrical parameters with biological responses and not with the avoidance of cell heating and cell death, Simon's teachings with regard to electroporation cannot meet the claim limitations. There is nothing in Simon that would teach or suggest maintaining the constant current electrical pulse below a threshold, which is required by the claims.

For these reasons, Claims 15-17, 34-36, and 52-54 are patentably distinct from Claims 21-23 of the '693 Patent, in view of Schwartz, Simon, and Fewell.

## VI. Conclusion

Applicant respectfully submits that, in light of the foregoing comments and amendments, all pending claims are now in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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